REMARKS

Claims 1-63, 65, 66, 69-84 are pending herein, claims 81-84 having been added and claims 64, 67 and 68 having been cancelled.

Presently pending claims 7, 8, 14, 17-23, 26, 27, 33, 39-49, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, and 75-79 are withdrawn from consideration by virtue of applicant's species election.

Claim 15 has been amended to provide explicit antecedent basis for the balloon in claim 16.

Support for the amendment to claim 50 and new claim 84 is found, for example, in claim 64 and in the specification (see, e.g., Figs. 1A-C, 2A-B and 25 and associated discussion).

Support for new claims 81-83 is found, for example, in paragraphs [0052] and [0068] of the specification.

No new matter is added.

Rejection of claims 1-6, 9, 12, 13, 15, 16, 24, 25, 28, 29, 34, 36-38, 50, 54, 56, 57, 61, 64, 71, 72 and 80 under 35 U.S.C. 102(e) over Maseda et al. US 6,514,237 (Maseda)

Claims 1-6, 9, 12, 13, 15, 16, 24, 25, 28, 29, 34, 36-38, 50, 54, 56 57, 61, 64, 71, 72 and 80 have been rejected under 35 U.S.C 102(e) as being anticipated by Maseda. Applicant respectfully traverses this rejection and its supporting comments.

Claim 64 has been cancelled.

For a reference to anticipate a claim it must disclose each an every element of the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (Fed. Cir. 1978). Also see MPEP 2131.

The independent claims are claims 1, 28 and 50. Each will be discussed in turn.

Claim 1

In claim 1, an active region is provided, which comprises a *conductive polymer*. The active region is disposed over an elongate body of the device such that the medical device is expanded in at least one radial dimension upon *volumetric expansion of the active region*.

Conductive polymers are discussed in more detail in paragraphs [0048] to [0050]. As noted therein, mass transfer of ions into and out of conductive polymer material (e.g., transfer

from and into an ionically conductive electrolyte medium associated with the electroactive polymer) leads to the volumetric expansion or contraction of the polymer. For further information, see e.g., H. Sahoo et al., "Actuators based on electroactive polymers," *Current Science,* Vol. 81, No. 7, 10 October 2001, 743-746, attached hereto, e.g., at page 743.

The actuators of Maseda, on the other hand, are ionic polymer metal composites, which typically consist of an ion-exchange membrane upon which is deposited a noble metal such as platinum. See, e.g., H. Sahoo et al. at 744-745. These actuators are classified differently in the electroactive polymer art from conductive polymer actuators, and they operate in a different fashion from conductive polymer actuators. *Id.* For example, when a voltage is applied, an electric field is set up inside the polymer causing the ions (e.g., cations) within the polymer, along with associated hydrated water molecules, to move within the polymer towards one of the electrodes (e.g., the cathode), which movement of within the polymer produces a bend in the EAP towards the other electrode (e.g., the anode). *Id.* Being self contained, such actuators do not undergo volumetric expansion, as do conductive polymers, but rather undergo deformation in the form of bending. *Id.*

Thus, the reference does not teach "each and every element" of claim 1 and fails as an anticipation of that claim.

Claim 28

Claim 28 is directed to a medical device that comprises (a) an elongate body adapted for insertion into a body lumen; (b) a balloon; and (c) an active region comprising an electroactive polymer disposed over the elongate body and beneath the balloon. The active region is adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state.

Nothing resembling this device is taught in Maseda. For example, Maseda does not appear to describe a device wherein the active region is adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state—much less one in which an active region comprising an electroactive polymer is disposed over the elongate body and beneath the balloon.

As noted in the present specification, for example, in paragraphs [0002], [0018] and [0070], current balloon catheters can be described as hydraulic systems. Hydraulic systems,

however, are more efficient at larger dimensions, and the present trend to downscale device sizes has created the need for actuators that efficiently function at very small diameters. An advantage of the present invention is that medical devices can be provided in which hydraulic expansion mechanisms are supplemented, thereby allowing these devices to operate efficiently at very small diameters. For example, by radially advancing at least a portion of a balloon outward from a fully crimped state, the balloon enters into a more efficient operating range, where less pressure is required to generate the large strains that are afforded by hydraulic actuation of this type.

Thus, here again, the reference does not teach each and every element of claim 28 and fails as an anticipation of that claim.

Claim 50

Claim 50 is directed to a device comprising: (a) an insertable body adapted for insertion into a body lumen of a patient; (b) a device lumen within said insertable body; (c) an inflatable balloon, the interior of which balloon is in fluid communication with the device lumen, and (d) one or more electrically actuated members disposed along at least a portion of the length of the device lumen. The electrically actuated members, which are adapted to transform at least a portion of the length of the device lumen between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into the body lumen of the patient.

Nothing resembling such a device is taught in Maseda. While Figs. 5 and 5A might arguably illustrate a device lumen (in conjunction with outer tubular body 114) that is transformable between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into the body lumen of the patient, the device lumen is clearly not in fluid communication with the interior of the balloon due to the presence of the slits that exist between the circumferentially spaced composite strands 500.

Claims 2-6, 9, 12, 13, 15, 16, 24, 25, 34, 36-38, 54, 56 57, 61, 71, 72 and 80 are patentable for at least the same reasons as the independent claims from which they depend, among other reasons. For example, contrary to the Office Action, the composite strands 306, 308, 400 of Maseda do not radially expand the tubular body 114—they stiffen, bend or twist the tubular body. Nor does Maseda describe a circumferential *band* (i.e., an annulus), rather the

strand pointed to in the Office Action is wrapped in a *helical manner*. Maseda does not describe a device in which at least a portion of the balloon is expanded from a first position to a second position that is radially beyond the first position upon expansion of one or more active regions—rather Maseda teaches that composite strips 500, which are constrained from movement on their ends, can expand "like a balloon" as illustrated in FIG. 5A, allowing the size and shape of the balloon-like structure to be varied. Maseda also teaches that the "balloon 118 ... may incorporate the composite strands," but does not teach or suggest that such strands would be used to radially advance/expand the balloon.

Reconsideration and withdrawal of the rejection under 35 U.S.C. 102(e) is respectfully requested.

Rejection of claims 10, 11, 30-32, 35 52, 60, 63, 73 and 74 under 35 U.S.C. 103(a)

Claims 10, 11, 30-32, 35 52, 60, 63, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda. This rejection is respectfully traversed.

The fundamental defects of the Maseda reference have been discussed above. With respect to these claims, the examiner has acknowledged that specific limitations have not been "directly" taught. The examiner's reasoning for a conclusion of obviousness is that the device disclosed by the reference is capable of carrying the functions recited in the present claims or could be modified in such a way as to result in the present claims. However that is not the valid criterion for obviousness, i.e., "capable of" and "could be modified" are not the same as "obvious to." See *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (BPAI 1993).

Claims 10, 11, 30-32, 35 52, 60, 63, 73 and 74 are patentable for at least the same reasons as the independent claims from which they depend, among other reasons.

It is noted that the mesh material of Maseda is part of the active material in a particular form and location to carry out a particular function in front of the balloon. Thus it can not "perform the function of a passive deformable region" as stated by the examiner. With regard to claims 60, 73 and 74, a disclosure of "various other configurations" does not make any specific undisclosed configuration obvious, absent some explanation based on logic and sound scientific reasoning. *Ex parte Levengood supra*. On this record there is no such explanation.

Reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a) are respectfully requested.

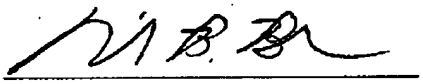
CONCLUSION

In light of the foregoing remarks, it is believed that all rejections of record have been obviated, and allowance of this application is respectfully requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

FEES

The Office is authorized to charge any fees that are due as a result of this Response, to the undersigned attorney's PTO Deposit Account #50-1047.

Respectfully submitted,



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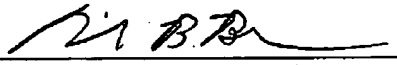

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